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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HUI SAN MING R	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
08/04/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/790,662	CHAPLIN ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendments filed April 2, 2009 have been entered.

Claims 1-16, 34-42, and 57 are pending.

As the elected specie is found free of art, the search is extended, in this instance, to all of the stilbene compounds with ortho-catechol moieties.

Claims 5-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected specie, there being no allowable generic or linking claim.

The outstanding rejection under 35 USC 112, first paragraph of claims 1-16, 34-42, and 57 is withdrawn. The examiner notes that the rejection under 35 USC 112, first paragraph is maintained. Applicant's arguments will be addressed below.

Claims 1-4, 10-16, 34-42, and 57 have been examined to the extend they read on the elected subject matter.

The new grounds of rejections are also set forth below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for ZSB-71 and some of the exemplified examples that are related to ZSB-71 that can be demonstrated to be capable of reducing the

blood flow to tumor region, does not reasonably provide enablement for other quinine, quinine, and catechol, compounds or their prodrugs for such properties. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. In the instant case, the instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to provide information allowing the skilled artisan to ascertain these compounds possessing the recited, and claimed, physiological activity without undue experimentation.

1) the quantity of experimentation necessary,

. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all " quinine, quinine, and catechol, compound(s)", necessitating an exhaustive search for all embodiments, regardless their chemical formula, or structure, suitable to practice the claimed invention. Examiner notes the claims read on all compounds possessing the envisioned physiological activity, disclosed , or undisclosed, regardless the structural formula of these compounds. Additionally, those compounds seen as encompassing such physiological activity must be experimentally discovered by the skilled artisan.

2) the amount of direction or guidance provided,

In the instant case, only a limited number of "quinine, quinine, and catechol, compounds" examples are set forth, thereby failing to provide sufficient working examples. Those compounds disclosed in the instant specification encompass only a small number of those compound classes envisioned as possessing physiological activity required to practice the invention as herein claimed. Absent that small genus of compounds herein recited, the instant specification is silent as to making, or using, those other compound genera encompassed by the instant claims. Although the specification directs the skilled artisan to specific quinine, quinine, and catechol, compounds compounds such as "ZSB 71", the application is silent with regard to selection of any additional compounds structurally unrelated to those few compounds listed in the instant specification.

3) the presence, or absence, of working examples,

Applicant fails to set forth the criteria that structurally defines, or identifies, those compounds possessing activity of "selectively reduce the blood flow to tumor region". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of "quinine, quinine, and catechol, compounds" examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define those structural classes of compounds required to practice the invention as herein claimed, as required by those guidelines set forth in *In re Wands*, supra. Absent exemplification providing guidance as to these compound classes herein envisioned, the instant specification fails to place those compound classes possessing various structural formulas requiring specific activity of selectively reduce blood flow to the tumor region in the skilled artisan's possession, absent undue experimentation.

4) the nature of the invention,

The instant invention reading on all possible compounds possessing the blood flow reducing activity envisioned, disclosed, or undisclosed, set forth a broad inventive scope. Claims herein presented require all compounds, regardless of structural formula, suspected of possessing the instant recited blood flow reducing activity to be assayed individually for their suitability in practicing the invention herein recited.

5) the state of the prior art,

The instant claims read on all "quinine, quinine, and catechol, compound(s)", necessitating an exhaustive search for the embodiments suitable to practice the claimed

invention. Although various individual compounds possessing the disclosed blood flow reducing activity are known to those of skill in the art, no information is provided to guide the skilled artisan to those diverse genera of structurally divergent compounds possessing similar physiological activity. Examiner is unaware of any nexus, stated in the art, or herein disclosed, attributing the herein envisioned physiological activity to one, or another, structural formula. Simply stated the skilled artisan must employ experimentation to discover compounds possessing these recited activities required to practice the claimed invention.

6) the relative skill of those in the art

Those individuals skilled in the art possess the required knowledge to perform those assays employed to identify compounds useful for practicing the invention as herein claimed. Applicants' failure to provide adequate guidance as to the envisioned structural formulas employed in the instant claims requires the skilled artisan to establish, by individual assay, each compound deemed suitable for use in the instant invention.

7) the predictability of the art,

The pharmaceutical art is generally unpredictable, requiring each embodiment to be individually assessed for physiological activity. The skilled artisan must teat each compound against the envisioned biochemical lesion to determine the possible use of such compounds in the instant invention.

8) the breadth of the claims.

. The instant claims read on all "quinine, quinine, and catechol, compounds", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Examiner notes the instant claims fail to provide any guidance as to those structural embodiments inherent in those compounds possessing the blood flow reducing activity herein envisioned. Applicant's claims encompass every, and all, compounds providing the recited blood flow reducing activity regardless the structural formula of such compounds. Absent guidance with regard to the structural identifies of those compounds possessing the recited blood flow reducing activity, each compounds must be identified by experimentation in every case. Applicants fail to provide information sufficient to identify the structural formulas of those compounds useful to practice the claimed invention, absent undue experimentation.

Response to Arguments

Applicant's arguments with respect to claims 1-3 have been considered but are moot in view of the new ground(s) of rejection. The examiner notes that ZSB-71 is considered enabled since it has been shown to have the recited blood flow reducing activity.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

> by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4, 10-16, 34-42, and 57 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,919,324 ('324).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

'324 teaches ZSB-36A and ZSB-37A (See col. 27 and col. 28).

Claims 4, 10-16, 34-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Blum et al., Biochemistry, 2000;39;15705-15712.

Blum et al. teaches a silbene compound, AG1233, meeting the herein claimed limitations (See page 15708, Table D).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 10-16, 34-42, and 57 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,919,324 ('324). Although the conflicting claims are not identical, they are not patentably distinct from each other because '324 teaches a small genus of compounds that encompasses the prodrug of the herein claimed compounds (See especially claim 5). One of ordinary skill in the art would have been motivated to employ any of the '324 compounds, including the one recited herein, in order to use them to treat cancer.

Claims 1-4, 10-16, 34-42, and 57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-13 and 23 of copending Application No. 11/112,055 ('055). Although the conflicting claims are not identical, they are not patentably distinct from each other because '055 teaches a small genus of compounds that encompasses the prodrug of the herein claimed compounds (See especially claims 10 and 23). One of ordinary skill in the art would have been motivated to employ any of the '055 compounds, including the one recited herein, in order to use them to destroy proliferating vasculature.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon - Fri from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Examiner
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